



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DFW

In re Mayumi KOTANI et al.

Group Art Unit: 1614

Application No.: 10/537,339

Examiner: Not Yet Assigned

Filed: June 2, 2005

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Confirmation No.: 3456

Customer No.: 42798

SUBMISSION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Commissioner for Patents
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 2234

Sir:

Applicants submit herewith a copy of the English translation of the International Preliminary Examination Report issued for the basic PCT application (PCT/JP2003/015572) of the above-referenced application.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Date: January 27, 2006

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Translation

PATENT COOPERATION TREATY

PCT/JP2003/015572



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-137	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/015572	International filing date (day/month/year) 05 December 2003 (05.12.2003)	Priority date (day/month/year) 06 December 2002 (06.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 35/78, 31/122, 31/353, 31/355, 31/7016, A61P 3/06, 3/10, 7/00, 39/06, 43/00, A23L 1/212, 1/30		
Applicant SUNSTAR INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 30 April 2004 (30.04.2004)	Date of completion of this report 11 November 2004 (11.11.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 18-23

because:

☒ the said international application, or the said claims Nos. 18-23
relate to the following subject matter which does not require an international preliminary examination (*specify*):

SEE SUPPLEMENTAL SHEET

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 18-23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The inventions set forth in claims 18-23 pertain to
methods for treatment of the human body by therapy.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4, 7, 8, 11, 13, 14, 17	YES
	Claims	1-3, 5, 6, 9, 10, 12, 15, 16	NO
Inventive step (IS)	Claims		YES
	Claims	1-17	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations

- Document 1: JP 2002-119265 A (Sunstar Inc.), 23 April 2002 (Family: none)
- Document 2: JP 2000-169382 A (Sunstar Inc.) 20 June 2000 (Family: none)
- Document 3: JP 2000-300224 A (Nippon Del Monte Corp.), 31 October 2000 (Family: none)
- Document 4: Oita Nosuisanbutsu Kako Sogo Shido Center Shiken Seiseki Hokokusho, 1997, Vol. 1996, pp. 5-8
- Document 5: Nippon Shokuhin Kagaku Kogaku Kaishi, 1998, Vol. 45, No. 2, pp. 138-144
- Document 6: J. Agric. Food Chem., 1998, Vol. 46, No.10, pp. 4118-4122
- Document 7: Nippon Shokuhin Kagaku Kogaku Kaishi 2001, Vol. 48, No. 4, pp. 246-252
- Document 8: J. Agric. Food Chem. 2002, Vol. 50, No. 23, pp. 6910-6916
- Document 9: JP 11-1686 A (Yoshihide Hagiwara), 6 January 1999; paragraph [0008], (Family: none)
- Document 10: JP 61-112024 A (KK Horiuchi), 30 May 1986 (Family: none)
- Document 11: JP 2002-238536 A (Marine Bio Co., Ltd.), 27 August 2002 (Family: none)
- Document 12: JP 4-8256 A (Junko Ebata), 13 January 1992

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(Family: none)

Document 13: JP 2000-219880 A (Taiyo Kagaku Co., Ltd.), 8
August 2000 (Family: none)

Document 14: JP 2002-308768 A (Fuji Chemical Industry Co.,
Ltd.), 23 October 2002 (Family: none)

Document 15: JP 2002-226368 A (Fuji Chemical Industry Co.,
Ltd.), 14 August 2002 (Family: none)

Document 16: JP 10-276721 A (Suntory Ltd.) 20 October 1998
(Family: none)

Document 17: JP 2002-275018 A (Kose Corp.), 25 September
2002 (Family: none)

Document 18: Shokuhin Kogyo Shidosho Kenkyu Hokoku 2002,
Vol. 16, pp. 4-9

Document 19: JP 2002-153210 A (Yukio Ishikura), 28 May
2002 (Family: None)

Document 20: JP 2002-360205 A (Kikkoman Corp.), 17
December 2002 (Family: none)

Document 21: JP 2002-275076 A (KK Toyo Shin'yaku), 25
September 2002 (Family: none)

Document 22: JP 2000-229834 A (Kanebo, Ltd.), 22 August
2000 (Family: none)

Document 23: JP 6-199687 A (Morinaga Milk Industry Co.,
Ltd.), 19 July 1994 (Family: none)

Document 24: J. Food Science 2002, Vol. 67, No. 5, pp.
1654-1659

Document 25: J. Nutrition 2000, Vol. 130, No.9, pp.
2200-2206

Document 26: J. Agric Food Chem., 1999, Vol. 47, No.4, pp.
1576-1581

Document 27: Tohoku Nogyo Kenkyu, 1994, No. 47, pp. 317-
318

Document 28: Kyoto-fu Eisei Kenkyu Nenpo, 1986, No. 52,
pp. 69-71

Document 29: JP 2001-299305 A (Bizen Kasei KK), 30 October
2001 (Family: none)

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Document 30: JP 2002-220340 A (Ito En, Ltd.), 9 August
2002 (Family: none)

Document 31: JP 2001-270832 A (Ito En, Ltd.), 2 October
2001 (Family: none)

Document 32: WO 98/33494 A1 (John V. Kosbab), 6 August,
1998; claim 6 & JP 2001-511153 A

Document 33: Planta, 1999, Vol. 207, No. 4, pp. 604-611

Documents 1-33 above are cited in the international search report.

Documents 1-4 disclose compositions described in claims 1-3 and 5, containing green and yellow vegetables such as broccoli, spinach, parsley and carrots, and light coloured vegetables such as lettuce, cabbage and celery used as food. Document 5 also discloses the fact that aforementioned compositions have antioxidant activity, so that document 5 substantially discloses the inventions set forth in claims 6, 9, 10, 12, 15 and 16. Therefore, the inventions set forth in claims 1-3, 5, 6, 9, 10, 12, 15 and 16 are not novel and do not involve an inventive step.

Documents 5-12, 18, 19 and 29 disclose the fact that the various vegetables cited in claim 2 have antioxidant activity and/or act to lower active oxygen; documents 13-17, 19 and 20-23 disclose the fact that the various constituents cited in claim 4 have antioxidant activity and/or act to lower active oxygen, and documents 21, 30 and 31 disclose the use of antioxidants which include aforementioned constituents in the management of diabetes and/or resulting complications. In addition, documents 26-28 disclose the fact that vegetables cited in claim 2 are rich in vitamin E, and documents 24, 25 and 33 disclose the fact that vegetables cited in claim 2 lower TBARS levels. Moreover, the interrelationships among

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antioxidant activity, suppression of peroxidized lipid, lowering of active oxygen, vitamin E content and therapeutic effects on TBARS levels or diabetic complications were known in the art before the filing date of the present application. Therefore, given the disclosures in the aforementioned documents of the fact that vegetables cited in claim 2 contain vitamin E and/or flavonoids, or that the aforementioned vegetables have some of the interrelated activities above, such as antioxidant activity, discovery of antioxidant activity, suppression of peroxidized lipid, lowering of active oxygen, vitamin E content and therapeutic effects on TBARS levels or diabetic complications in each of the vegetables is an option within the ordinary competence of a person skilled in the art. Moreover, the description does not appear to describe any marked effect due to combining the constituents mentioned above. Therefore, the inventions set forth in claims 1-17 do not involve an inventive step, because they could be deduced easily by a person skilled in the art with reference to the art disclosed in documents 1-33 above.